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PTO/SB/21 (02-04) Approved for use through 07/31/2006. OMB 0651-0031

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nder the Paperwork Reduction Act of 1995, no persons are required to resp	ond t	o a co	ollectio	n of inform	mation uni	less it displa	ys a valid Of	MB contro	I number.

#### Application Number 10/750,570 Filing Date **TRANSMITTAL** December 30, 2003 First Named Inventor **FORM** Reddy, Satyanarayana G. Art Unit 1614 (to be used for all correspondence after initial filing) **Examiner Name** Not Yet Assigned Attorney Docket Number Total Number of Pages in This Submission 60188CON2(49947) 1 ENCLOSURES (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Technology Center (TC) Appeal Communication to Board of Fee Attached Licensing-related Papers Appeals and Interferences Appeal Communication to TC Amendment/Reply Petition (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final **Proprietary Information Provisional Application** Power of Attorney, Revocation Affidavits/declaration(s) Status Letter Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request Terminal Disclaimer identify below): **Express Abandonment Request** Request for Refund x | Information Disclosure Statement CD, Number of CD(s) Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Form PTO/SB/08a/b (3 pages); Incomplete Application Certificate of Express Mailing (1 page); Response to Missing Parts Information Disclosure Statement (2 pages, in duplicate); under 37 CFR 1.52 or 1.53 Copies of references A18, A19 and B4; Transmittal (1 page) and; Return Receipt Postcard SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT EDWARQS & ANGELL, LLP Peter C. **) )**auro - 32,360 Individual name Signature Date July 12, 2004

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Docket No.: 60188CON2(49947)

(PATENT)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reddy, Satyanarayana G.

JUL 1 2 2004

Application No.: 10/750570

Filed: December 30, 2003 Art Unit: 1614

(Peter C. Lauro, Esq.)

For: Cyclic Ether Vitamin D3 Compounds,

1α(OH)3-EPI-Vitamin D3 Compounds and

Uses Thereof

Examiner: Not Yet Assigned

Confirmation No.: 5729

### **INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.56 and 1.97, Applicant hereby invites the Examiner's attention to the references listed on the attached form PTO/SB/08, in connection with the examination of the above-identified patent application. Applicant respectfully requests that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This application is a continuation application of application serial no. 10/188,320, filed on July 1, 2002, abandoned, which is a continuation application of serial no. 09/617,881, filed on July 17, 2000, issued as U.S. Patent 6,479,538, which is a divisional application of application serial no. 09/079,942, filed on May 15, 1998, issued as U.S. Patent 6,100,294, which in turn claims priority to provisional application serial no. 60/046,690, filed on May 16, 1997.

Copies of references A18, A19 and B4 listed on the PTO/SB/08 are enclosed. Pursuant to 37 C.F.R. §1.98(d), copies of the remaining references listed on the PTO/SB/08 are

Application No.: 10/750570 2 Docket No.: 60188CON2(49947)

not enclosed because these references were submitted to, or cited by, the Office in information disclosure statements filed in one or more of the above-identified priority applications, and those statements complied with paragraphs (a)-(c) of 37 C.F.R. §1.98

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Under 37 C.F.R. § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 C.F.R. §1.17(p) to our Deposit Order Account No. 04-1105. A duplicate of this statement is enclosed.

Dated: July 12, 2004

Peter C. Lauro, Esq.

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tfally submitt

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many she ets as necessary)

Sheet 1 of 3

	Complete if Known				
Application Number	10/750570				
Filing Date	December 30, 2003				
First Named Inventor	Reddy, Satyanarayana G.				
Art Unit	1614				
Examiner Name	Not Yet Assigned				
Attorney Docket Number	60188CON2(49947)				

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	4,021,423	05/77	Baggiolini et al.	
	A2	4,038,272	07/77	Partridge, Jr. et al.	
	A3	4,188,345	08/80	DeLuca et al.	
	A4	4,206,131	06/80	Salmond	
	A5	4,595,776	06/86	Baggiolini et al.	
	A6	4,711,881	12/87	Ikekawa	
	A7	4,804,502	02/89	Baggiolini et al.	
	A8	5,145,846	06/92	Baggiolini, deceased et al.	
	A9	5,206,229	04/93	Calverley et al.	
	A10	5,206,230	04/93	Ikekawa et al.	
	A11	5,389,622	02/95	Posner et al.	
	A12	5,401,733	03/95	McLane et al.	
	A13	5,428,029	06/95	Doran et al.	
	A14	5,547,947	08/96	Dore et al.	
	A15	5,789,607	08/98	Okabe	
	A16	5,824,811	10/98	Kubodera et al.	
	A17	5,830,885	11/98	Posner	
	A18	6,100,294	08/00	S.G. Reddy	
	A19	6,479,538	11/02	S.G. Reddy	

		FORE	GN PATENT	DOCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	B1	EP 808,831	11/97			
	B2	EP 808,833	11/97	İ		
	В3	FR 2545824 A	11/84			
	B4	AU 743514	05/02	S.G. Reddy		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.usplo.gov">www.usplo.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3.). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is

	NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
-	C1	Baggiolini, E. et al., "Stereocontrolled Total Synthesis of 1α25-Dihydroxycholecalciferol and 1α,25-Dihydroxyergocalciferol," <i>J. Org. Chem.</i> 51:3098-3108 (1986)		
	C2	Bishop, J. et al., "Profile of Ligand Specificity of the Vitamin D Binding Protein for 1α,25- Dihydroxyvitamin D <sub>3</sub> and its Analogs," <i>J. Bone &amp; Mineral Res.</i> 9(8): 1277-88 (1994)		

Examiner	Date	
Signature	Considered	

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Su	Substitute for form 1449A/B/PTO			Complete if Known		
	545511415 15 15 15 15 15 15 15 15 15 15 15 15 1		Application Number	10/750570		
11	NFORMATIO	N DI	SCLOSURE	Filing Date	December 30, 2003	
8	STATEMENT BY APPLICANT		First Named Inventor	Reddy, Satyanarayana G.		
				Art Unit	1614	
	(Use as many s	he ets as	necess ary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number	60188CON2(49947)	

Mineral Res. 8(8):1009-15 (1993)	C3	Bouillon, R. et al., "Biologic Activity of Dihydroxylated 19-Nor-(Pre) Vitamin D <sub>3</sub> ," J. Bone &
Endocrine Reviews 16(2): 200-57 (1995)   C5   Campbell, M. et al., "Vitamin D <sub>3</sub> Analogs and Their 24-Oxo Metabolites Equally Inhibit Clonal Proliferation of a Variety of Cancer Cells but Have Differing Molecular Effects," <i>J. Cellular Biochem.</i> 66:413-25 (1997)   C6   Cota, J.G. et al. "Hydrotitanation-Protonation of Vitamin D <sub>2</sub> and Its Analogues: An Efficient Method for the Preparation of 10,19-Dihydrovitamins D <sub>2</sub> Including Dihydrotachysterol <sub>2</sub> " <i>Journal of Organic Chemistry</i> 53(26):6094- (1988).   C7   Cross, H. et al., "Vitamin D Metabolism in Human Colon Adenocarcinoma-derived Caco-2 Cells: Expression of 25-Hydroxyvitamin D <sub>3</sub> -1α-hydroxylase Activity and Regulation of Side-chain Metabolism," <i>J. Steroid Biochem. Molec. Biol.</i> 62(1):21-8 (1997)   C8   de Vos, S. et al., "Effects of Potent Vitamin D <sub>3</sub> Analogs on Clonal Proliferation of Human Prostate Cancer Cell Lines," <i>The Prostate</i> 31(2):77-83 (1997)   C9   Dusso, A.S. et al., "On the Mechanisms for the Selective Action of Vitamin D Analogs," Endocrinology 128(4):1887-92 (1991)   C10   Fioravanti, L. et al., "Synthetic Analogs of Vitamin D <sub>3</sub> Have Inhibitory Effects on Breast Cancer Cell Lines," <i>Anticancer Research</i> 18.1703-8 (1998)   C11   Fleet, J. et al., "1α, 25-(OH) <sub>2</sub> -Vitamin D <sub>3</sub> Analogs with Minimal in Vivo Calcemic Activity Can Stimulate Significant Transepithelial Calcium Transport and mRNA Expression in Vitro," <i>Archives of Biochem. &amp; Biophysics</i> 329(2):228-34 (1996)   C12   Fleet, J.C. et al., "Effect of A-Ring Diastereomers of 1α, 25-Dihydroxy Vitamin D <sub>3</sub> on Calcium Transport in Caco-2 Cells," <i>FASEB J.</i> 9(3):168 (1995)   C13   Gardner, J. et al., "Vitamin D Analog 25-(OH)-16,23E-Diene-26,27-Hexafluoro-Vitamin D <sub>3</sub> Induces Differentiation of HL60 Cells with Minimal Effects on Cellular Calcium Homeostasis," <i>J. Cellular Biochem.</i> 63:500-12 (1996)   C14   Jung, S. et al., "1,25(OH) <sub>2</sub> -16ENE-Vitamin D <sub>3</sub> is a Potent Antileukemic Agent with Low Potential to Cause Hypercalcemia," <i>Leukemia Research</i> 18(6):453-63 (1994)   C15   Kim, H. et		
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Cells: Expression of 25-Hydroxyvitamin D <sub>3</sub> -1α-hydroxylase Activity and Regulation of Sidechain Metabolism," <i>J. Steroid Biochem. Molec. Biol.</i> 62(1):21-8 (1997)  C8 de Vos, S. et al., "Effects of Potent Vitamin D <sub>3</sub> Analogs on Clonal Proliferation of Human Prostate Cancer Cell Lines," <i>The Prostate</i> 31(2):77-83 (1997)  C9 Dusso, A.S. et al., "On the Mechanisms for the Selective Action of Vitamin D Analogs," <i>Endocrinology</i> 128(4):1687-92 (1991)  C10 Fioravanti, L. et al., "Synthetic Analogs of Vitamin D <sub>3</sub> Have Inhibitory Effects on Breast Cancer Cell Lines," <i>Anticancer Research</i> 18:1703-8 (1998)  C11 Fleet, J. et al., "1α,25-(OH) <sub>2</sub> -Vitamin D <sub>3</sub> Analogs with Minimal in <i>Vivo</i> Calcemic Activity Can Stimulate Significant Transepithelial Calcium Transport and mRNA Expression in <i>Vitro</i> ," <i>Archives of Biochem.</i> & <i>Biophysics</i> 329(2):228-34 (1996)  C12 Fleet, J.C. et al., "Effect of A-Ring Diastereomers of 1α,25-Dihydroxy Vitamin D <sub>3</sub> on Calcium Transport in Caco-2 Cells," <i>FASEB J.</i> 9(3):168 (1995)  C13 Gardner, J. et al., "Vitamin D Analog 25-(OH)-16,23E-Diene-26,27-Hexafluoro-Vitamin D <sub>3</sub> Induces Differentiation of HL60 Cells with Minimal Effects on Cellular Calcium Homeostasis," <i>J. Cellular Biochem.</i> 63:500-12 (1996)  C14 Jung, S. et al., "1,25(OH) <sub>2</sub> -16ENE-Vitamin D <sub>3</sub> is a Potent Antileukemic Agent with Low Potential to Cause Hypercalcemia," <i>Leukemia Research</i> 18(6):453-63 (1994)  C15 Kim, H. et al., "1,25-Dihydroxy-Vitamin-D <sub>3</sub> Enhances Antiproliferative Effect and Transcription of TGF-β1 on Human Keratinocytes in Culture," <i>J. Cellular Physiol.</i> 151:579-87 (1992)  C16 Lemire, J. et al., "1,25-Dihydroxy-24-OXO-16ene-Vitamin D <sub>3</sub> , a Renal Metabolite of the Vitamin D Analog 1,25-Dihydroxy-24-OXO-16ene-Vitamin D <sub>3</sub> . A Metabolite of Vitamin D <sub>3</sub> Made in the Kidney," <i>Biochemistry</i> 22)(8):1798-1895 (1983)  C19 Norman, A. et al., "23,25-Dihydroxy-24-oxovitamin D <sub>3</sub> : A Metabolite of Vitamin D <sub>3</sub> Made in the Norgenomic but not Genomic Biological Responses and Biological Profile of the Three A-ring Diastereomers	C6	Method for the Preparation of 10,19-Dihydrovitamins D <sub>2</sub> Including Dihydrotachysterol <sub>2</sub> " <i>Journal of Organic Chemistry</i> 53(26):6094- (1988).
C8    de Vos, S. et al., "Effects of Potent Vitamin D <sub>3</sub> Analogs on Clonal Proliferation of Human Prostate Cancer Cell Lines," The Prostate 31(2):77-83 (1997)	C7	Cells: Expression of 25-Hydroxyvitamin D <sub>3</sub> -1α-hydroxylase Activity and Regulation of Side-
<ul> <li>C9 Dusso, A.S. et al., "On the Mechanisms for the Selective Action of Vitamin D Analogs," Endocrinology 128(4):1687-92 (1991)</li> <li>C10 Fioravanti, L. et al., "Synthetic Analogs of Vitamin D<sub>3</sub> Have Inhibitory Effects on Breast Cancer Cell Lines," Anticancer Research 18:1703-8 (1998)</li> <li>C11 Fleet, J. et al., "10,25-(OH)<sub>2</sub>-Vitamin D<sub>3</sub> Analogs with Minimal in Vivo Calcemic Activity Can Stimulate Significant Transepithelial Calcium Transport and mRNA Expression in Vitro," Archives of Biochem. &amp; Biophysics 329(2):228-34 (1996)</li> <li>C12 Fleet, J.C. et al., "Effect of A-Ring Diastereomers of 1α,25-Dihydroxy Vitamin D<sub>3</sub> on Calcium Transport in Caco-2 Cells," FASEB J. 9(3):168 (1995)</li> <li>C13 Gardner, J. et al., "Vitamin D Analog 25-(OH)-16,23E-Diene-26,27-Hexafluoro-Vitamin D<sub>3</sub> Induces Differentiation of HL60 Cells with Minimal Effects on Cellular Calcium Homeostasis," J. Cellular Biochem. 63:500-12 (1996)</li> <li>C14 Jung, S. et al., "1,25(OH)<sub>2</sub>-16ENE-Vitamin D<sub>3</sub> is a Potent Antileukemic Agent with Low Potential to Cause Hypercalcemia," Leukemia Research 18(6):453-63 (1994)</li> <li>C15 Kim, H. et al., "1,25-Dihydroxy-Vitamin-D<sub>3</sub> Enhances Antiproliferative Effect and Transcription of TGF-β1 on Human Keratinocytes in Culture," J. Cellular Physiol. 151:579-87 (1992)</li> <li>C16 Lemire, J. et al., "1,25-Dihydroxy-24-OXO-16ene-Vitamin D3, a Renal Metabolite of the Vitamin D Analog 1,25-Dihydroxy-24-OXO-16ene-Vitamin D3, a Renal Metabolite of the Kidney," Biochemistry 22)(8):1798-1805 (1983)</li> <li>C17 Mayer, E. et al., "23,25-Dihydroxy-24-oxovitamin D<sub>3</sub>: A Metabolite of Vitamin D<sub>3</sub> Made in the Kidney," Biochemistry 22)(8):1798-1805 (1983)</li> <li>C18 Muralidharan, K.R., "Studies on the A-Ring Diastereomers of 1Alfa, 25-Dihydroxyvitamin D<sub>3</sub>," J. Organic Chem. 58(7):1895-1899 (1993)</li> <li>C19 Norman, A. et al., "Demonstration That 1β,25-Dihydroxyvitamin D<sub>3</sub> is an Antagonist of the Nongenomic but not Genomic Biological Responses and Bi</li></ul>	C8	de Vos, S. et al., "Effects of Potent Vitamin D <sub>3</sub> Analogs on Clonal Proliferation of Human
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Examiner	· ·	Date	
Signature		Considered	 

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Sub	Substitute for form 1449A/B/PTO			Complete if Known		
<u></u>		Application Number	10/750570			
INFORMATION DISCLOSURE		Filing Date	December 30, 2003			
STATEMENT BY APPLICANT		First Named Inventor	Reddy, Satyanarayana G.			
		Art Unit	1614			
	(Use as many s	he ets as i	necess ary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	60188CON2(49947)	

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reddy, Satyanarayana G.

Application No.: 10/750570

Confirmation No.: 5729

Filed: December 30, 2003

Art Unit: 1614

For:

JUL 1 2 2004

Cyclic Ether Vitamin D3 Compounds,

1α(OH)3-EPI-Vitamin D3 Compounds and

Uses Thereof

Examiner: Not Yet Assigned

### **INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.56 and 1.97, Applicant hereby invites the Examiner's attention to the references listed on the attached form PTO/SB/08, in connection with the examination of the above-identified patent application. Applicant respectfully requests that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This application is a continuation application of application serial no. 10/188,320, filed on July 1, 2002, abandoned, which is a continuation application of serial no. 09/617,881, filed on July 17, 2000, issued as U.S. Patent 6,479,538, which is a divisional application of application serial no. 09/079,942, filed on May 15, 1998, issued as U.S. Patent 6,100,294, which in turn claims priority to provisional application serial no. 60/046,690, filed on May 16, 1997.

Copies of references A18, A19 and B4 listed on the PTO/SB/08 are enclosed. Pursuant to 37 C.F.R. §1.98(d), copies of the remaining references listed on the PTO/SB/08 are

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not enclosed because these references were submitted to, or cited by, the Office in information disclosure statements filed in one or more of the above-identified priority applications, and those statements complied with paragraphs (a)-(c) of 37 C.F.R. §1.98

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Under 37 C.F.R. § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 C.F.R. §1.17(p) to our Deposit Order Account No. 04-1105. A duplicate of this statement is enclosed.

Dated: July 12, 2004

Peter C. Lauro, Esq.

Respectfully submit

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